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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Markus Luy

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08/01/2008

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

08/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,965	LUY ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/14/06; 4/18/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I, claims 1-13, drawn to a method for cultivating microorganisms belonging to *Thraustochytriales*, in the reply filed on 5/06/2008 is acknowledged.

The traversal is on the ground(s) that the rest of the claims (claims 14-20) are dependent on claim 1 and, thus, these claims 14-20 are directed to species. This argument is not found persuasive because claims 14-20 are directed to various and several products-obtained-by-process which are clearly different invention categories and different from a process. Moreover, claims 14-20 are directed to more than one of permissible combinations of categories of inventions such as more than one product including oils having different characteristics, purified DHA and DPA preparations, biomass, animal feed and foodstuff. A “special technical feature” (that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art) is known in the prior art as evidenced by Bajpai et al. teaching cultivation of microorganisms of the genus *Thraustochytriales* in a fermentation medium with CaCO₃ (at “materials and methods” and Fig. 1). Thus, unity of inventions is lacking. See MPEP 1850. 37 CFR 1.475.

With regard to claims 18-20, in particular, applicants argue that the claimed biomass preparation is made by a process that requires special concentrations of calcium carbonate and, thus, results in accumulation of greater amounts of beneficial lipids and/or oils. Yet, the product by process claims are not limited to the manipulations steps. Although the use of different cultivation media might lead to different effects including various accumulations of beneficial

products, the methods of concentration and purification of the products of interest are well within the purview of ordinary skill practitioner.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction requirement in the reply filed on 5/06/2008.

Claims 1-13 are under examination in the instant office action.

Information Disclosure Statement

Some of the references cited on IDS do not indicate the dates of publication. Please, correct.

Claim Rejections - 35 USC § 112

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 provides for the use of a cultivation medium for cultivating a microorganism, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

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parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,582,941 (Yokochi et al), US 6,509,178 (Tanaka et al), EP 0 113 183 (IDS reference) and Bajpai et al. (IDS reference).

Claims are directed to methods for cultivating microorganisms belonging to *Thraustochytriales* wherein the method comprise step of cultivating microorganisms belonging to *Thraustochytriales* in a fermentation medium comprising calcium carbonate in amounts 3-15 g/L as means for pH control. The claimed cultivation method is intended for production of oils, DHA and DPA. Some claims are further drawn to cultivation conditions such as pH 3-10, temperature between 10 and 40 degree C and cultivation time 1-10 days. Some claims are further drawn to the use of fermentation medium comprising glucose, corn steep liquor, potassium hydrogen phosphate, ammonium sulfate, magnesium and calcium chloride, calcium carbonate and sodium sulfate. Some claims are further drawn to culturing microorganisms belonging to *Thraustochytriales* such as *Schizachytrium* sp. strain SR21 and *Ulkenia* sp. strain SAM 2179.

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US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al) teach methods for cultivation of microorganisms belonging to *Thraustochytriales* as intended for production of DHA and DPA. The cited methods include cultivation of the *Thraustochytriales* representatives such as *Schizachytrium sp.* strain SR21 (US 6,582,941 at abstract and table 7) and *Ulkenia sp.* strain SAM 2179 (US 6,509,178 at abstract and table 1). The disclosed cultivation conditions are within the presently claimed ranges of cultivation conditions that they include pH 4-6.5 temperature between 10 and 35 degree C and cultivation time 3-7 days. The disclosed fermentation media contain same nutrients as required by the claimed invention including glucose, corn steep liquor, potassium hydrogen phosphate, ammonium sulfate and sea salts that comprise magnesium and calcium chloride, calcium carbonate and sodium sulfate at least to some extent. For example: see US 6,582,941 at col. 10, lines 66-67; col.11, lines 1-3; col.18, lines 14-20. For example: see US 6,509,178 at col. 7, lines 50-57; col. 8, lines 1-14.

The method of the cited patents result in accumulation or production of more than 10% DHA per biomass weigh and more than 1 % of DPA per biomass weigh. For example: US 6,582,941 discloses accumulation or production by SR21 strain of more than 10% DHA per weigh or about 17 % (table 7; 54% total fat per weight and 34 % DHA per total fat). The cited US 6,509,178 also discloses accumulation or production by SAM 2179 strain of more than 10% DHA per weigh and more than 1 % DPA (table 1).

The cited patents US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al) teach pH control during cultivation of microorganisms belonging to *Thraustochytriales* but the cited references only disclose the use of a generic suitable acid and/or base material, thus, being silent about calcium carbonate as material for pH adjustments.

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However, EP 0 113 183 teaches the pH control during microbial cultivation with pH controlling material such as calcium carbonate (see abstract) including concentrations 0.5-5 g/L in fermentation medium (page 9, lines 9-11). Further, the reference by Bajpai et al. teaches cultivation of microbial representatives of *Thraustochytriales* in a fermentation medium with calcium carbonate (at “materials and methods” and Fig. 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use calcium carbonate as pH controlling material during cultivation of microorganisms belonging to *Thraustochytriales* with a reasonable expectation of success in culturing the microorganisms belonging to *Thraustochytriales* because the prior art prior art teaches the use of calcium carbonate as pH controlling material as adequately taught by EP 0 113 183 and because microorganisms belonging to *Thraustochytriales* have been cultured in the presence of calcium carbonate as intended for oils, DHA and DPA production as evidenced by Bajpai et al. The claimed specific strains SR 21 and SAM 2179 have been known and used in the fermentation methods as intended for oils, DHA and DPA production as adequately demonstrated by US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

July 30, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657